

## **REMARKS/ARGUMENTS**

### **Status of the claims**

With entry of this amendment, claims 2,3, and 11-14 are cancelled. Claims 1, 4-10, 15, and 16 are currently pending. Support for the amendments can be found throughout the specification, original claims and figures. These amendments add no new matter.

### **Election/Restrictions**

The Examiner has stated that affirmation of the election made by telephone must be made in Replying to the Office Action. The Applicant hereby affirms the election made by telephone conversation on 1/27/09.

### **Claim Objections**

The Examiner objected to claims 1-16 because the claims contained references to non-elected invention. With entry of these amendments, the claims have been restricted to the currently elected invention.

### **Claim Rejections Under 35 USC §112 Second Paragraph**

The Examiner rejected claims 7 and 10 as allegedly as being allegedly indefinite.

Without acquiescing to the rejection, and solely to expedite prosecution, Applicants have amended claim 7 to remove the word “hybridizing” from the phrase “said hybridizing step d)” so that there is proper antecedent basis for the claim. Claim 10 has been amended to rephrase the language, and Claim 9 (from which Claim 10 depends) has been amended to depend from Claim 8. Thus there is currently proper antecedent basis for the limitations in Claim 10

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 USC §112, Second Paragraph.

### **Claim Rejections Under 35 USC §103**

The Examiner rejected claims 1-3 as allegedly unpatentable over Manaresi et al (“Manaresi”) in view of Hemauer et al. (“Hemauer”).

According to the Examiner, Manaresi discusses methods “comprising (a) providing a sample suspected to contain the target nucleic acid, (b) providing a pair of primers comprising a first and a second primer, (c) amplifying the target nucleic acid, and (d) detecting the amplified target nucleic acid of step (c).”

Also, the Examiner admits that Manaresi does not discuss the method “whereby the first primer has a nucleic acid sequence SEQ ID NO:15, and whereby the second primer has a nucleic acid sequence SEQ ID NO:17.”

Applicants respectfully points out that Hemauer does not compensate for the deficiency of Manaresi. Hemauer does not discuss the method whereby the first primer has a nucleic acid sequence SEQ ID NO:15, and whereby the second primer has a nucleic acid sequence SEQ ID NO:17.

The Examiner points out that Hemauer discloses a large region of the genomic sequence of Parvovirus B19, and that this large region encompasses SEQ ID NOS: 15 and 17. The Examiner also asserts that Hemauer teaches nearby primers to amplify this region.

However, Hemauer does not teach primers within the large conserved NS1 region, let alone primers of SEQ ID NOS: 15 or 17.

The Examiner asserts that Hemauer teaches that the large conserved region shows positive results relative to other regions of Parvovirus B19. The Examiner then asserts that it would have been obvious to one of skill in the art to use primers of SEQ ID NOS:15 and 17 (which are not disclosed anywhere in Hemauer) to modify and perform the methods described in Manaresi.

Applicants respectfully point out, again, that primer sequences of SEQ ID NOS: 15 or 17 are disclosed nowhere in Hemauer. Further, Hemauer actually uses primers outside the NS1-C region to amplify the target area. Thus, there is no suggestion in either Manaresi or

Hemauer to use primers of sequence SEQ ID NOS:15 or 17, and claims 1-3 cannot be considered obvious under Manaresi and Hemauer.

The Examiner also rejects claims 1-5 and 8-14 under 45 U.S.C. 103(a) as allegedly obvious un Schmidt et al (“Schmidt”) in view of Hemauer.

Claims 2, 3, and 11-14 have been cancelled. Thus the Examiner’s rejection is now currently concerned with claims 1, 4, 5, and 8-10.

In the rejection, the Examiner makes a similar argument with regard to Hemauer, stating that Hemauer teaches a conserved region of Parvovirus B19 which encompasses SEQ ID NOS:11, 15, and 17. However, Hemauer does not disclose any primers or probes comprising sequences SEQ ID NOS: 11, 15, or 17. The Examiner also states that Hemauer teaches nearby primers to amplify the region, but does not teach primers within the conserved region.

The Examiner cites In Re Deuel, stating that the Fed. Circ. determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious., but that structural or functional homolog may provide a requisite motivation.

However, even in light of In Re Deuel, Hemauer does not disclose primer of SEQ ID NOS: 11, 15, or 17. Further, the primers taught in Hemauer aren’t functionally equivalent to those in the current invention, as the primers for amplification taught by Hemauer fall outside the conserved NS1-C region. Contrary to the Examiner’s assertion, the claimed primers are not structural homologs of any sequences cited in Hemauer. The Examiner has not demonstrated the *prima facie* case of obviousness.

The Examiner further cites the MPEP 2144.06 noting that “equivalency must be recognized in the prior art, and cannot be based on applicant’s disclosure or the mere fact that the components at issue are functional or mechanical equivalents.”

Here, the Examiner appears to be doing just that which the MPEP prohibits, basing the equivalency of the primers and probe in the instant invention on the Examiner’s argument that “the mere fact that the components at issue are functional or mechanical equivalents.” While the Applicant disputes the Examiner’s argument that the primers are functional or structural equivalents, even if they were to be functional equivalents, the equivalency is not demonstrated by the prior art.

The Examiner further goes on to cite Buck, in which a single experiment demonstrated that large number of control primers for a completely different target were functionally equivalent. The Examiner erroneously states that “(t)his clearly shows that every primer would have a reasonable expectation of success.”

This is grossly incorrect. Buck does not concern itself with the conserved region of NS1-C in Parvovirus B19, but with an unrelated target. Further, it has been well established that primers in different regions do not function equivalently, and are highly dependent on several factors (eg. binding conditions, and nucleotide composition in the region, *inter alia*). However, even if each primer would have the expectation of success, the Examiner has still not demonstrated any primer equivalent in Buck, Hemauer, or Schmidt. As stated previously, Hemauer does not teach any primers within the conserved NS1-C region. Despite the Examiner’s use of capitalization with the phrases “EVERY SINGLE PRIMER” and “EVERY SINGLE CONTROL PRIMER,” the combination of Hemauer and Buck does not teach nor provide equivalents to primers or probes with the sequence of SEQ ID NOS: 11, 15, or 17.

Finally, the Examiner rejected claims 1-7, 9, and 10-14 under 35 U.S.C. 103(a) as allegedly obvious under Harder et al (“Harder”), Hemauer, and Buck.

Without reiterating the Examiner’s argument’s, the Applicant’s respectfully point out that, Harder, nor Hemauer or Buck, as previously stated, teach any primer or probe sequence with SEQ ID NOS: 11, 15, or 17, or any equivalents thereof. Thus, the prima facie case of obviousness has not been made with the addition of Harder.

The Examiner rejected claim 15 as allegedly obvious under 35 U.S.C. 103(a) in view of (I) Hemauer, Buck, and Schmidt, or in view of (II) Hemauer, Buck and Harder, and further Andrus et al. (“Andrus”).

Without reiterating the Examiner’s argument, the combination of Hemauer and Buck NOT satisfy the prima facie case of obviousness. Their deficiencies are not met by Schmidt, Harder or Andrus. Thus, the Examiner has failed to demonstrate obviousness.

The Examiner rejected claim 16 as allegedly obvious under 35 U.S.C. 103(a) in view of (I) Hemauer, Buck, and Schmidt, or in view of (II) Hemauer, Buck and Harder, and further Mosquera et al. (“Mosquera”).

Without reiterating the Examiner's argument, the Combination of Hemauer and Buck NOT satisfy the prima facie case of obviousness. Their deficiencies are not met by Schmidt, Harder or Mosquera. Thus, the Examiner has failed to demonstrate obviousness.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 USC §103.

### **CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

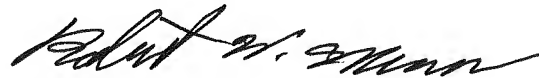
If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-730-8560.

### **Extension of Time**

Under 37 CFR §1.136(a), Applicants respectfully request a 3-month extension of time to respond to the Office Action mailed March 5, 2009. The response date was June 5, 2009, and with the granting of this request, the response time is re-set to September 5, 2009. The commissioner is hereby authorized to charge the fee due under 37 CFR §1.136(a), to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this amendment and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,



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Date: August 31, 2009

### **Correspondence Address**

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